C5 - 7

COMPACT PROSTHETIC TOTAL HEART

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When an irreversibly diseased organ is to be replaced with an artificial device, it is appropriate that the device be inserted in or very near that organ's natural site. The heart is one of those organs which makes such orthotopic placement possible. The pericardial sac offers a place ideally suited to the mechanical heart, as it separates it completely from adjacent organs thus preventing mutual stress. Since its function is entirely concerned with the hemodynamics of pulmonary and systemic circulation, prosthetic connections between the artificial heart and natural counterparts should be as short as possible. In the past, many factors, such as unsuitable surgical and manufacturing techniques and inadequate construction materials, have been obstacles in making a mechanical heart which could be implanted comfortably and safely inside the pericardial sac.

The first such a heart for intrapericardial implantation, called "composite heart," was designed by the author (T. A.) and reported by SenGupta(1) et al. for use in calves. A modified type has since been reported by Nose et al(2). This paper describes a new type of intrapericardial prosthesis designed for use in dogs.

DESCRIPTION

The heart is of the sac type and is driven by compressed air. Every effort was made to design it as compactly as possible, especially longitudinally. From the standpoint of clot prevention inside the heart, it is preferable to make each side all of one piece, as in the Silastic heart previously reported by the author(3). The great disadvantage of this method, however, is that the entire unit has to be replaced even when slight breakage of an essential part occurs.

In our mechanical heart, both ventricles, atria, aorta, pulmonary artery and valves are made separately, assembled partially before the experiments, and then assembled completely during the process of insertion so that every segment can be taken apart after each experiment and cleaned for re-use (Figure 1). The left ventricle is cylindrically shaped, and the right ventricle is flat with a slight curve. Both have the same volume of about 50 ml. When they are combined and the vessels connected, the right ventricle embraces the left, the aorta pointing upward at an angle of 45^{o} between the inlet and the outlet valves of the right ventricle. The pulmonary artery passes the center line between the inlet valves of both ventricles around the aorta, pointing downwards (Figure 2). The combined atria have wide openings, and their edges are supplied with multi-fold Dacron mesh which is used to provide a secure continuous anastomosis to the natural atria. The vessels are provided with a metal ring, embedded in plastic, for rapid connection. The heart has been constructed of two different materials, one, a mixture of polyurethane and colloidal graphite, and the other, Silastic. The former is treated with benzalkonium chloride and heparin before use. In both, the outer housing is rigid. Liquid aluminum was used to give rigidity to the polyurethane-graphite unit which was then completely covered with plain polyurethane, and the Silastic heart, resin-coated Fiberglass then completely covered with Silastic.

Three different types of valves have been utilized: tricusp semilunar valves made of a mixture of polyurethane and colloidal graphite (Figure 1), Silastic tricusp semilunar valves built into a vessel (Figure 3), and butterfly-type valves (Figure 4). By using the second valve we were able to eliminate one connection. In the Lexan* ring of the third valve treated by Gott's method(4) we have eliminated the center bridge. The leaflet made of Silastic was reinforced partially with a half-round stainless steel plate to prevent it from everting.

DRIVING UNIT

Our driving unit controls the following parameters: pulse rate, duration of systole and diastole, air pressure, and suction (Figure 5). The timer has two main dials with digital figures, indicating the duration of systole and diastole in milliseconds. Air pressures and suctions on both sides are shown on each gauge in millimeters of mercury. Pulse rates can be determined easily from a table in each com-

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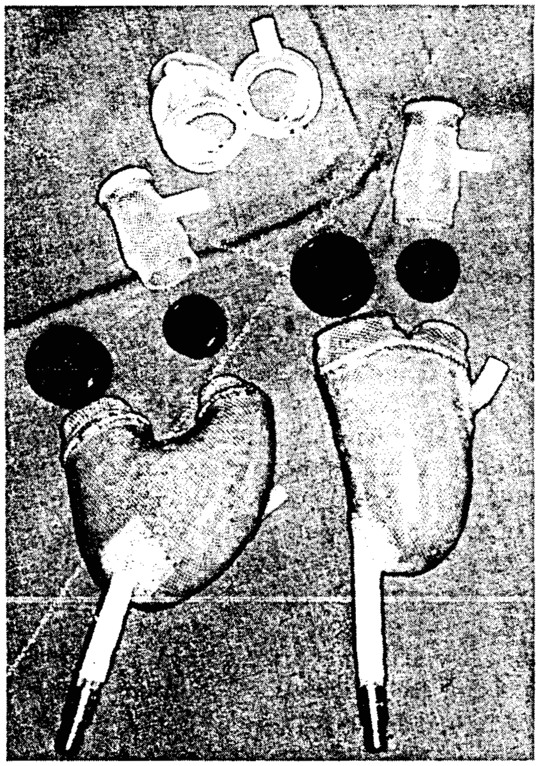

Figure 1. Parts of Silastic heart.
Top: Combined atria
Left: Triangular flat right ventricle
Right: Cylindrical left ventricle
Middle: Pulmonary artery, aorta, and two inlet (large) and two outlet (small) tricusp semilunar valves. Valves are made of mixture of polyurethane and colloidal graphite.

Figure 2. Assembled Silastic heart.
Slightly curved right ventricle (right) embraces cylindrical left ventricle. Aorta points upwards at an angle of 45° between right atrium and pulmonary artery (top).

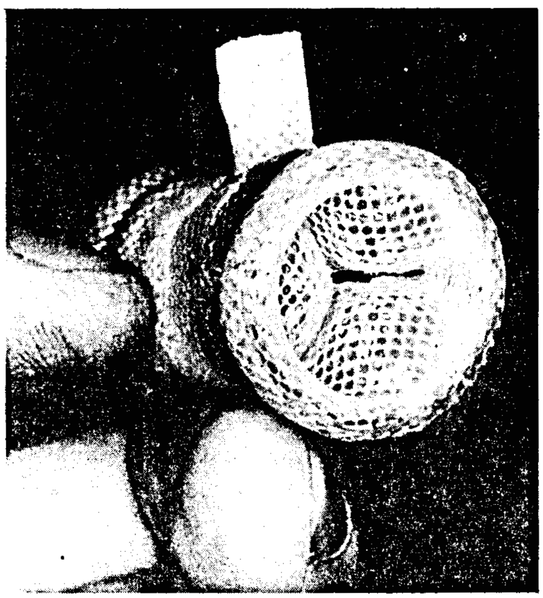

Figure 3. Silastic vessel with built-in tricusp semilunar valve.

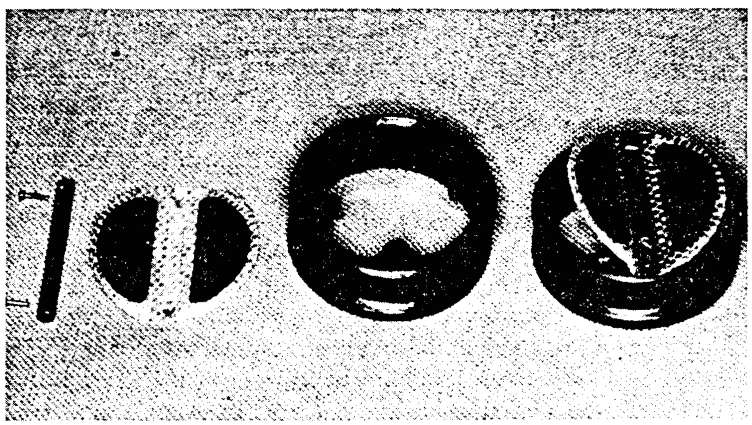

Figure 4. Butterfly-type valves. Left: Screws and stainless steel bar coated with colloidal graphite; Silastic leaflet with two pieces of embedded stainless steel plate provided to prevent leaflet from everting. Lexan ring. Right: assembled valve.

bination of systole and diastole. From a practical standpoint, durations were changed by increments of 25 msec. The system has two different reservoirs in the pressure lines. One is placed between the pressure gauge and the three-way solenoid valve. This stabilizes the pressure in the line, and gives accelerating initial pressure. The other was inserted in the line between the solenoid valve and the artificial heart to alleviate sharp rise and fall of pressures.

TESTS

In six different models, each with slight modifications, both ventricles were tried in a test circulatory system. In order to find out the characteristics of our heart, cardiac outputs were determined in one left heart model at 324 points of combinations of systole and diastole with each increase of 25 msec. starting from 125 msec. up to 550 msec. This covered the pulse rate range from 55 to 218. The least amount of air pressure which could produce flows from 3.0 to 3.5 L./min. was used. We found that the peak flow on each line of the same pulse rate stays within the range of the ratio of systole and diastole (S/D), between 1.5 to 0.75 under the conditions used. The S/D decreases as the duration of diastole increases. The change of flow in pulse rates from 92 to 120, which were mostly used in dog experiments, is shown in Figure 6 in relation to the S/D. Until the S/D of 0.8 there is no difference in flows according to the pulse rate. The difference reaches maximum at peak flows in each pulse rate which appear at S/D 1.4 to 1.5. The flow peak comes slightly later in higher pulse rates than in lower pulse rates. Thus the area of the combinations of systole and diastole where cardiac outputs of about 3 L./min. necessary for 30 Kg. dogs was found to be under those conditions described in Figure 6. Flow determinations were made under other conditions--with less air pressures and less suctions. It was found that when the outlet valve with less resistance was used, even air pressure of 150 mm. Hg (suction -30 mm. Hg) could give 3.0 to 3.5 L./min. of cardiac output under identical conditions. In addition, the flow peaks in the pulse rates from 92 to 120 shifted to S/D 1.0.

The pumping conditions of the right ventricle was determined the same way, pumping against less pressure head--20 cm. H_2O. In dog experiments, however, ventricular pressure curves revealed a sharp initial peak and fall below 0 at the beginning of diastole. In order to eliminate these, a damping reservoir was installed in the air line between the three-way solenoid valve and the prosthesis. In actual tests with different volumes it was determined from the ventricular pressure curves that 200 ml. on the left side and 300 ml. on the right side are adequate. By adding these reservoirs and applying less suction, peak flows in each pulse rate shifted further to the left where the S/D is 0.5 (Figures 7 and 8). On the right side, active suction was not even used. Sharp rise and fall in the ventricular pressure curves have been completely eliminated.

EXPERIMENTS

Thirteen implantation experiments (polyurethane hearts in three, Silastic hearts in ten) have been done in dogs weighing from 28 to 35 Kg. Anesthesia was induced by intravenous injection of Nembutal (30 to 40 mg./Kg./body weight), and the chest entered through the fourth intercostal space. During insertion of the mechanical heart, the dog's circulation was maintained by a heart-lung machine which consists of one roller pump and a homologous lung obtained from a donor dog after exanguination. Heparin (3.0 mg./Kg./body weight) intravenously administered prior to cannulation was neutralized with 1.5 times of protamine after cessation of extracorporeal circulation. After the natural heart was removed the mechanical heart was connected in the following order: combined atria, right ventricle with two valves attached before surgery, left ventricle with valves, aorta attached to the left ventricle, and pulmonary artery to the natural pulmonary artery first and then to the right ventricle. During implantation, the bronchial return was drained back to the reservoir in the extracorporeal circuit. Upon removal of air from each chamber after completion of connection to the natural counterparts, as the mechanical heart started pumping, extracorporeal circulation was stopped simultaneously. The side tubes attached to each chamber were taken out through the chest wall and connected to a pressure transducer for continuous pressure monitoring.

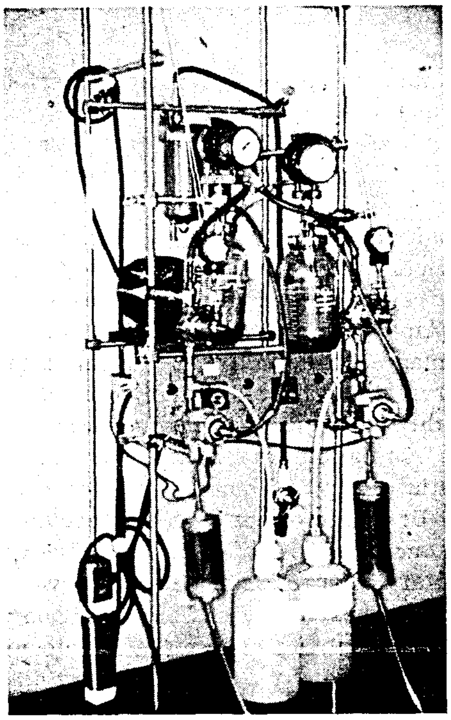

Figure 5. Driving unit. Each side has pressure gauge and vacuum gauge shown in mm. Hg. Two pressure regulators are located immediately after each opening of compressed air source, and at air filter. Four liter reservoirs are inserted before three-way solenoid valve. Both contribute to stabilization of the air pressure in line. Damping reservoirs (200 ml. for left heart, 300 ml. for right heart) inserted after solenoid valve eliminate sharp pressure changes in line. Timer has two dials, one for systole, the other for diastole, indicating their duration in milliseconds with digital figures.

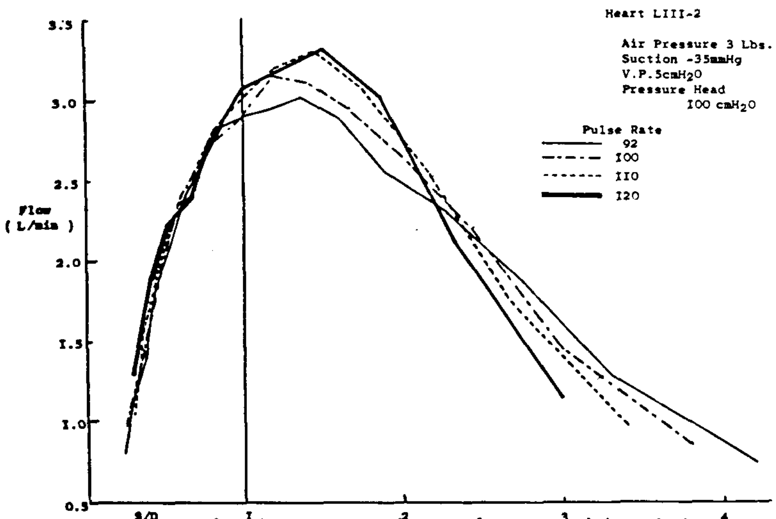

Figure 6. Relation of cardiac output and ratio of systole and diastole in one left ventricle determined in test circuit under conditions shown. Until S/D 1.0 all curves increase together regardless of pulse rates. Flow peaks appear at S/D 1.5 with a difference of 0.34 L./min. Flow peaks come later with faster pulse rates than with slower. After peak is reached the faster the pulse rate, the more rapid the decrease of flow.

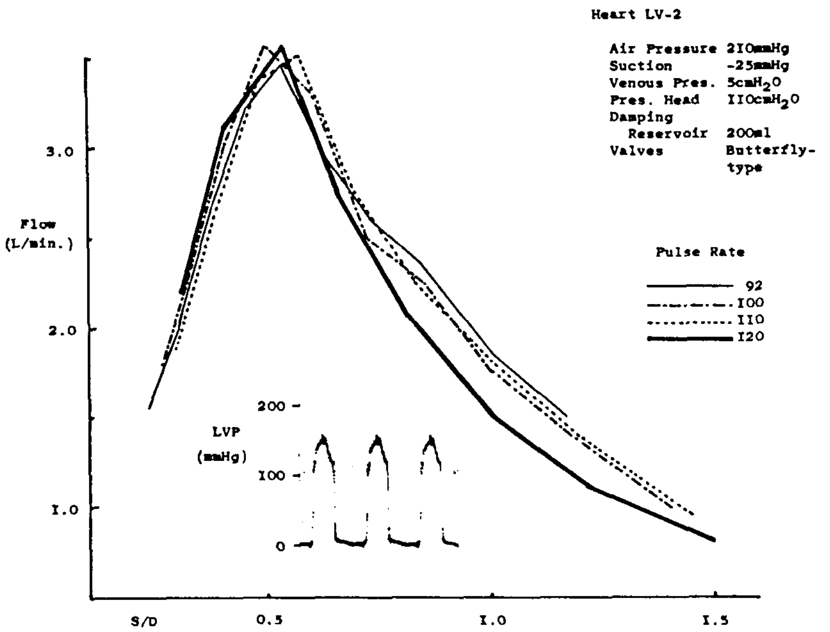

Figure 7. Relation between cardiac output and S/D ratio in one left ventricle determined in test circulatory system under conditions shown. Note that when S/D is less than 0.5, cardiac output changes almost exactly as the S/D ratio increases regardless of pulse rate. Flow peaks appear at S/D between 0.5 and 0.6.

RESULTS AND COMMENTS

Time of extracorporeal circulation varied from one hour, 15 min. to one hour, 46 min. Periods of from 51 to 75 min. were required from clamping of the aorta to completion of the connection of mechanical hearts. Time of mechanical heart pumping ranged from 15 min. to 27 hr. Several dogs were sacrificed even while they still had vital signs since no possibility of improvement in general condition was noted. Five dogs out of 13 survived longer than ten hours. The dog who survived for 27 hours completely recovered from anesthesia, and could stand and walk without any support. Sudden death was due to bleeding from 0.5 cm. long tear along the middle of the right atrial suture line. Bleeding in the chest cavity by leakage from the atrial suture line appears most frequently as the principal cause of death (Table I). Several methods of prevention have been tried. Among them, reinforcements of the anastomosis edge of the combined atria with an additional ridge made of Silastic sponge, a thin strip of the same material, 8-fold Dacron mesh, 4-fold Dacron mesh with a thin strip of Dacron felt inside, 4-fold Dacron mesh with a thin roll of oxidized cellulose inside. In three dogs the pericardium was involved in the anastomosis of the right atrium with the first method. In the others isobutyl cyanoacrylate manomer* was applied on the suture line. All methods have been satisfactory and no dog has been lost since from bleeding or air suction at the site of atrial anastomosis. Breakage of aortic valves occurred in one tricusp semilunar valve made of polyurethane-graphite and in one Silastic leaflet of butterfly-type valve. The former material is superior in anti-thrombogenicity to plain polyurethane. However, we have not found it a satisfactory material for this type of valve because of increase of stiffness and poor tear resistance. Two holes for screws which affixed the leaflet to the Lexan ring were made too close to the edge causing it to tear on one side. Eventually, however, the breakage of the Silastic leaflet was found to be preventable. Thrombosis caused one death after 11 hr. of pumping. All four valves were completely covered with thick thrombi on both sides. This appeared to be due to re-use of the same leaflets which had not been thoroughly cleaned. In all of the first seven experiments, thin thrombi were found along the edge of valve rings made of Lexan treated by Gott's method, even in dogs which died after six hours of pumping. However, subsequently the valves have been left in heparin solution until immediately before insertion into the heart, and no thrombi have been seen at least up to 14 hr.

TABLE I

CAUSES OF DEATH

A) Bleeding in chest cavity		8
by leakage from atrial suture line	(4)	
bleeding tendency	(2)	
tear of natural right atrium	(1)	
disconnection of aorta	(1)	
B) Breakage of mechanical heart parts		2
aortic valve	(2)	
C) Inadequate extracorporeal circulation		1
D) Air emboli		1
E) Thrombosis		1
leakage from atrial suture line		
	Total	13

Silastic vessels with a built-in tricusp semilunar valve have eliminated one connection procedure. The resistance to the flow in this valve, however, was found greater than in a butterfly-type valve although 12 Mil thick reinforced Silastic was used. In this series of experiments, buttefly-type valves gave the most satisfactory results. We have eliminated the center bridge of the ring thus decreasing material and reducing the chance of clot formation between the bridge and the leaflet. No breakage has been experienced in any other parts.

In testing mechanical hearts in relation to cardiac output, we fixed the venous pressure low at 5.0 cm. H_2O. It is well known that the higher the venous pressure, the greater the cardiac output up

*Ethicon, Inc., Somerville, New Jersey

to a certain point. However, in actual animal experiments, rather low venous pressure is encountered more often than high. In addition, high venous pressure does not always mean that the heart is pumping with a large cardiac output as seen in the test circulatory system. Instead, more often the heart has some defects and is not pumping as much blood as is returned. Therefore, we tried to locate the area of various combinations where each ventricle could pump the necessary amount of blood against resistance with a low inflow pressure. Since the prosthesis is only one size, we selected dogs of around 30 Kg. Therefore, efforts were made to find out the area of combinations of various determinant factors where the flow from 3.0 to 3.5 L./min. could be obtained. The method of testing in relation to the time factors was arranged so that each systole and diastole were changed with the increment of 25 msec. A table was then made in which time relation of systole and diastole, pulse rate, and ratio of systole and diastole could be instantly found. In the original driving unit the desired flow area appeared at the ratio of systole and diastole at around 1.5. With longer systoles stronger suction was needed making worse ventricular pressure curves with sharp rise and fall. By inserting a damping reservoir all these undesirable factors have been eliminated. The method of pumping became more physiological; smooth ventricular pressure curves appeared, and there was less jumping movement of the ventricles. Longer diastole at peak flows, regardless of pulse rate required less active suction, and caused more residual ventricular volume. In the right ventricle no active suction was needed, only the natural expanding force due to its design and the resilience of the material. This corresponds to the elastic recoiling of the natural ventricular wall, and was strong enough to suction sufficient blood for subsequent cardiac output.

SUMMARY

Compact mechanical hearts implantable inside the pericardial sac have been developed. They are driven by compressed air, and made of either a mixture of polyurethane and colloidal graphite or Silastic. Their rigid housing is made of either liquid aluminum of Fiberglass and resin.

A physiological method of pumping has been devised operated by a simple driving unit.

Thirteen experiments have been performed in dogs. One dog survived for 27 hr. and could stand and walk without support.

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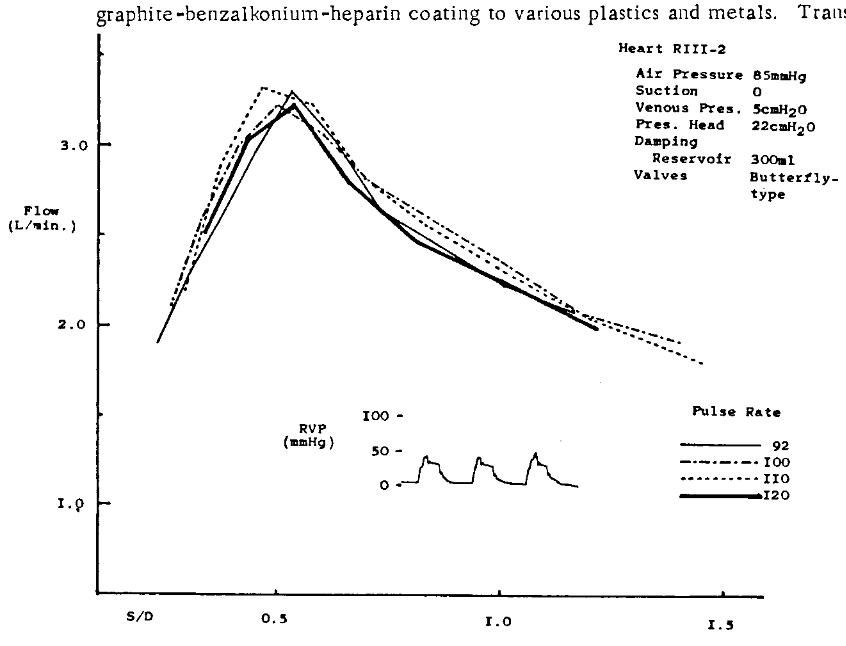

Figure 8. Relation between cardiac output and S/D ratio in one right ventricle determined in test circulatory system under conditions shown. Cardiac outputs change almost identically as the S/D ratio changes. Only a small difference in each pulse rate is noted. Flow peaks appear at S/D ratio 0.5.